U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Remote Monitoring
Prototype Use Case
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1.0 Preface

Use cases developed for the American Health Information Community (AHIC) are based on the priorities expressed by the AHIC workgroups. These high-level use cases focus on the needs of many individuals, organizations, and systems rather than the development of a specific software system. The use cases describe involved stakeholders, information flows, issues, and systems needs that apply to the multiple participants in these arenas.

The use cases strive to provide enough detail and context for detailed policy discussions, standards harmonization, certification considerations, and architecture specifications necessary to advance the national health information technology (HIT) agenda. These high-level use cases focus, to a significant degree, on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system.

During the January 2007 AHIC meeting, nine priority areas (representing over 200 identified AHIC and AHIC workgroup detailed priorities) were discussed and considered. Three of these areas (Consumer Access to Clinical Information, Medication Management, and Quality) were prioritized and developed into the 2007 Detailed Use Cases, which were published in June 2007. The Health Information Technology Standards Panel (HITSP) Technical Committees are currently conducting harmonization work on these use cases.

The remaining six priority areas from the January 2007 AHIC meeting were updated based upon AHIC feedback and were reviewed during the July 2007 AHIC meeting. These six priority areas are now being developed into the 2008 Use Cases (Remote Monitoring, Remote Consultation, Personalized Healthcare, Consultation and Transfers of Care, Public Health Case Reporting, and Immunizations & Response Management) which will be processed in the national HIT agenda activities in 2008.

The 2008 Use Cases are being developed by the Office of the National Coordinator for Health Information Technology (ONC) with opportunities for review and feedback by interested stakeholders within both the private and public sectors. To facilitate this process, the use cases are being developed in two stages:

- The **Prototype Use Cases** describe the candidate workflows for the use case at a high level, and facilitate initial discussion with stakeholders; and
- The **Detailed Use Cases** document all of the events and actions within the use case at a detailed level.

This document is a prototype use case, which describes at a high level the actors, capabilities, and information sharing needs associated with this use case. ONC is publishing the prototype use case at an earlier stage of development in order to incorporate more substantive input from interested stakeholders into the detailed use case.

The prototype use case is divided into the following sections:

- Section 2.0, Introduction and Scope, briefly describes the priority needs identified by one or more AHIC workgroups and preliminary decisions made about the scope of the use case.
- Section 3.0, Use Case Stakeholders, briefly describes individuals and organizations which participate in activities related to the use case and its components.
- Section 4.0, Issues and Obstacles, briefly describes issues or obstacles which may need to be resolved in order to achieve the capabilities described in the use case.
- Section 5.0, Perspectives, briefly describes how the use case combines similar roles (or actors) in order to describe their common needs and activities. The roles are intended to describe functional roles rather than organizations or physical entities.
- Section 6.0, Candidate Workflows, briefly describes how various perspectives interact and exchange information within the context of a workflow. The use case workflow model provides a context for understanding the information needs and is not meant to be prescriptive.
- Appendix A, the Glossary, provides draft definitions of key concepts and terms contained in the prototype.

Also within the prototype document are specific questions for which ONC would like to receive feedback during the development process. Following receipt of feedback from interested stakeholders, ONC will develop a detailed use case, which will incorporate the feedback received, fully describe the events and activities from a variety of perspectives, and include information flow diagrams.

2.0 Introduction and Scope

The ability for a clinician to remotely monitor a patient's vital signs and other physiological measurements and tests may be a key enabler for the management of chronic health problems. Measurement devices designed for use by the patient or a family member could communicate measurements to a clinician's electronic health record (EHR) and/or the patient's personal health record (PHR).

During remote monitoring, the clinician-patient relationship may benefit from a care coordination layer of support. This support could include a variety of tasks; some may be more clinical and could support the clinician, while others may be more patient-oriented, less clinical, and provided by family members or caregivers. "Care coordinators" could serve in this role and are likely to need access to detailed measurements, while clinicians may prefer summarized data, which may include trends in measurement and notifications. In specific terms:

- Patients and clinicians may benefit from the ability for the patient to gather and communicate physiological information electronically from measurement devices in a home or other non-clinical setting to a clinician's EHR system and/or to the patient's PHR. Physiological information could include weight, blood pressure, heart rate and rhythm, pulse oximetry, and glucose measurements.

- Interoperable, user-friendly technologies are needed to enable the flow of information between monitoring systems and the HIT of the clinicians responsible for their care.

- Remote care may imply the ability of clinicians to work across jurisdictional boundaries and use information generated by remote assessment (as opposed to in-person examination). This may be inhibited by administrative burden and legal concerns.

One of the goals of the AHIC is establishing a pathway, based on common data standards, to facilitate the incorporation of interoperable, clinically useful remote monitoring information into EHRs to support clinical decision-making. This use case was developed to support the many stakeholders who are active in the development and implementation of electronic health records and health information exchange including those engaged in activities related to standards, interoperability, harmonization, architecture, policy development, and certification.

The Remote Monitoring Prototype Use Case focuses on the exchange of physiological and other measurements from remote monitoring devices in three candidate workflows:

- **Measurement and Communication** - This candidate workflow is focused on using the remote monitoring device to gather and communicate physiological and other

measurements from the patient's location to the appropriate care coordinators and/or clinicians. The capture of patient data entered manually is also a part of this workflow.

- **Monitoring and Coordination** - This workflow is focused on the role of the care coordinator to monitor the information received from the remote monitoring device, communicate with the patient or caregiver, and inform the clinician if the measurements indicate a potential health issue.

- **Clinical Management** - This workflow is focused on the role of the clinician who evaluates the patient's health status based on the information received from the care coordinator and/or the remote monitoring devices.

This use case assumes the developing presence of electronic systems such as EHRs, PHRs, and other local or Web-based solutions supporting patients and clinicians, while recognizing the issues and obstacles associated with these assumptions. This approach helps promote the development of longer-term interoperability efforts.

3.0 Use Case Stakeholders

Figure 3-1. Remote Monitoring Use Case Stakeholders Table

Stakeholder	Working Definition
Care Coordinators	Health support personnel who provide assistance to patients and their surrogates in the management of health and disease conditions.
Clinical Decision Support Tool Providers	Organizations that provide tools to aid in the understanding and treatment of health and disease conditions. These tools encompass a wide range of capabilities that may be useful and available to patients, consumers, clinicians, and other health professionals.
Clinicians	Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in treating patients.
Consumers	Members of the public who may receive healthcare services. These individuals may include: caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient.
Health Researchers	Organizations or individuals who use health information to conduct research.
Healthcare Entities	Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health, school health, dental clinics, psychology clinics, care delivery organizations, and other healthcare facilities.
Healthcare Payors	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.
Medical Device Manufacturers/Suppliers	Organizations that design, build, sell, or support the use of medical devices by consumers to support their health needs with coordinated assistance from clinical and other health support personnel.
Patients	Members of the public who receive healthcare services.

ONC would like to receive feedback on the draft list of stakeholders and their descriptions for this use case. Please suggest additions, deletions and/or revisions to the description of the stakeholders.

4.0 Issues and Obstacles

The successful implementation of remote monitoring as a health care assessment and treatment tool is dependent on overcoming a number of issues and obstacles in today's health care delivery environment. Inherent in this use case is the premise that some of these will addressed through policy development, HIT standardization and harmonization activities, health information exchange (HIE) networks, and other related initiatives. While progress is being achieved on some of these concerns, a broad summary of relevant issues and obstacles to remote monitoring is included below.

Business Model

- Reimbursement
    - Health care clinicians may not be reimbursed for time spent with (and expertise provided to) patients to support the remote monitoring of their conditions outside of the office setting.
    - Patients may not be willing to invest in or use remote monitoring without the support of a health care clinician on a regular basis.
    - Payors may not be willing to reimburse patients for the purchase, operation, and maintenance of remote monitoring devices.

Confidentiality, Privacy, Security and Data Access

- Patient data confidentiality and privacy
    - Patients will want confidentiality, access control and information describing who has had access to their information.
    - The implementation of remote monitoring may include access to patient data by care coordinators.
- Security and data access
    - Personal health data must be appropriately secured whenever stored, transmitted, archived, or destroyed.
    - Where information is passed across multiple organizations or geographic regions, there will be compliance to applicable local, state, and federal regulations.

Medical Devices

- Devices and their use must be adequately understood by all parties involved in their use including patients, patient surrogates, clinicians, and care coordinators.
- Data outputs from devices must also be standardized so widespread use of devices and their data streams is possible with minimal customization of supporting systems. This may require a standardized nomenclature for describing these devices.
- Storage of information gathered by devices is not currently standardized and all potential information storage locations must adhere to appropriate security and confidentiality needs.

EHR and PHR Use

- Limited adoption of EHRs and PHRs may pose an obstacle to the use of remote monitoring.
- Where EHRs and PHRs exist, a standardized interface with remote monitoring technology may not, including determinations regarding the detail, structure, and quantity of patient information to be stored.

Medical Practice and State Laws

- Wide-spread remote monitoring may require analysis and change to existing laws and regulations related to treating/monitoring patients across jurisdictional borders.
- Medical practice may be inhibited by additional administrative burden and legal concerns.

Decision Support

Decision support tools can provide valuable assistance to patients, care coordinators, and clinicians who use remote monitoring to support health and disease management. Though these tools are not widely used today, they can provide support for:

- Patient education.
- Identification of conditions when face-to-face, follow-up, urgent, or emergency care should be sought.

- Recent research findings and “best practice” methods.

ONC would like to receive feedback on the draft list of issues and obstacles and their descriptions for this use case. Please suggest additions, deletions and/or revisions.

5.0 Use Case Perspectives

The Remote Monitoring Prototype Use Case focuses on the exchange of physiological and other test measurements between patient's monitoring devices and their clinicians (and the clinicians' supporting systems). The use case will describe remote monitoring from four perspectives. The perspectives are representative of roles and functions, rather than organizations or physical locations.

Each is described below:

- **Patient**

  The patient, caregivers, advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient, could use the remote monitoring device to gather physiological and other measurements. These measurements are then communicated to the appropriate clinicians either directly or via a communications service which could be provided by a device manufacturer or other entity. The patient measurements may be taken in various non-clinical settings such as at home, at work, at school, while traveling, or assisted living facilities.

- **Device Manufacturer**

  The device manufacturer perspective includes the manufacturer of a device who may, in some instances, provide a communications service, which gathers data from the device and makes detail and summary information available to care coordinators or clinicians who are monitoring the patient's measurements. This perspective also includes communications and support services that may be provided by someone other than the device manufacturer. A device manufacturer may provide these capabilities for a large number of patients who are all using the manufacturer's device. It is unlikely that the device manufacturer would provide this capability for all devices associated with a given patient.

- **Care Coordinator**

  The care coordinator perspective includes those individuals who monitor the information received from the patient's device(s) and could include both clinically-trained and/or non-clinical individuals. Care coordinators could include clinicians, nurses, caregivers, case managers, home health resources, family members and/or others. The care coordinator may follow-up with the patient, especially if measurements indicate that there has been a relevant change in the patient's health status, or if the measurements

fall outside of a predetermined range. The care coordinator may also inform the patient's clinician if measurements indicate a potential health issue. Finally, the care coordinator may help determine the need for an immediate face-to-face visit or urgent/emergency care. Any non-clinical care coordination activities would be managed by the clinician as a part of the plan of care.

- **Clinician**

The clinician perspective includes physicians, nurses, nurse practitioners, physician assistants, and other personnel who clinically evaluate the remote measurements and determine appropriate clinical interventions if needed.

These perspectives are the focus of the events described in the candidate workflows in Section 6.0.

ONC would like to receive feedback on the draft list of perspectives and their descriptions for this use case. Please suggest additions, deletions and/or revisions.

6.0 Candidate Workflows

The Remote Monitoring Prototype Use Case focuses on the exchange of physiological and other test measurements between patient's monitoring devices and their clinicians.

6.1 Measurement and Communication

This scenario is focused on using the remote monitoring device to gather and communicate physiological and other measurements from the patient's location to the appropriate care coordinators and/or clinicians.

- The patient or caregiver prepares the device for communications. This may involve registering the device with the manufacturer and/or configuring the communications capabilities of the device.
    - The ability to uniquely associate the device with the patient may be required if the device communicates directly to a manufacturer's database, other communications service, or an EHR. Devices which communicate via the patient's PHR may not require this step.
    - While the devices are intended for patient use, there may be a need for the device manufacturer or other service entity to provide some limited installation assistance.
    - Devices may have the ability to communicate interoperable information directly with an EHR or PHR, or may communicate in proprietary or other formats with a device manufacturer's or other entity's service.
- The patient or caregiver uses the remote monitoring device to gather and communicate measurements. Examples could include patient weight, heart rate and rhythm, pulse oximetry, and glucose measurements.
    - Measurements could be communicated each time the device gathers the data or the accumulated measurements could be communicated periodically (e.g., daily). For some types of devices, summary information may be communicated rather than individual measurements.
    - Measurements could be communicated to the device manufacturer, to the patient's PHR, to an EHR, or to another system.

- The device could provide immediate feedback to the patient or caregiver if a measurement indicates a potential change in health status which needs attention. Feedback could also be generated by the system receiving the measurements (e.g., manufacturer's (or other) database or EHR) based on predefined algorithms.

- In some instances, the device may be unable to perform the gathering and communications activity. In those instances, the patient or caregiver could manually gather the measurements and communicate them using a telephone keypad, PHR, web-based service, or other communications mechanism. These measurements could also be communicated using secure messaging or other technologies. Secure messaging is discussed further in the Remote Consultation Use Case.

6.2 Monitoring and Coordination

This scenario is focused on the role of the care coordinator to monitor the information received from the remote monitoring device, communicate with the patient or caregiver, and inform the clinician if the measurements indicate a potential health issue. It should be noted that the care coordinator and clinician could be the same person.

- With appropriate safeguards for patient privacy and security, the care coordinator could review the measurement information received in an EHR, or in a device manufacturer's or a third party database. Measurement information could be provided in detail or summary form (e.g., measurement trends).

- Clinical decision support algorithms may be available to assist the care coordinator as the information is reviewed to identify possible health issues which may require additional evaluation by clinically qualified individuals.

- Care coordinators may interact directly with the patient or caregiver to verify the information received and gather additional information about the patient's situation. Relevant disease management clinical decision support may be available to the care coordinator to assist in evaluating the situation and determining whether a clinician should be informed.

- If needed, care coordinators may inform a clinician of the patient's health status and situation, providing appropriate summary information. If the clinician and care coordinator are not using the same EHR, this exchange of information could occur via telephone, structured messaging, or other interactive technology.

6.3 Clinical Management

This scenario is focused on the role of the clinician who evaluates the patient's health status based on the information received from the care coordinator and/or the remote monitoring devices.

- The clinician reviews information received from the care coordinator describing the patient's health status and/or measurements. The clinician may access and review other patient clinical information such as current medications during this process. Upon completing their review, the clinician may determine that a change in the care plan is needed.
- The clinician may choose to communicate their assessment and plan of care to the care coordinator or directly to the patient or caregiver.
    - This information may be communicated to a care coordinator's EHR and, in some instances, the patient's PHR.
- The clinician documents the clinical activity.
- The care coordinator may also communicate with the patient or caregiver regarding the plan of care.
- The care coordinator may also document the clinical activity.

ONC would like to receive feedback on the candidate workflows. Should any changes be made to the descriptions of these interactions? For those candidate workflows listed, is the working definition of key information sources and recipients sufficient? If not, what changes should be made?

ONC would like to receive feedback on whether individual data measurements or summary data should be considered as part of the legal medical record.

Appendix A: Glossary

AHIC: American Health Information Community.

Care Coordinators: Health support personnel who provide assistance to patients and their surrogates in the management of health and disease conditions.

Clinical Decision Support Tool Providers: Organizations that provide tools to aid in the understanding and treatment of health and disease conditions. These tools encompass a wide range of capabilities that may be useful and available to patients, consumers, clinicians, and other health professionals.

Clinicians: Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in treating patients.

CMS: Centers for Medicare & Medicaid Services, a federal agency within the Department of Health and Human Services.

Consumers: Members of the public who may receive healthcare services. These individuals may include: caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient.

Department of Health and Human Services (HHS): This is the federal agency responsible for human health, and has oversight over many other federal agencies such as FDA, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), CMS, the Agency for Health Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), and others.

Electronic Health Record (EHR): The electronic health record is a longitudinal electronic record of patient health information generated in one or more encounters in any care delivery setting. This information may include patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory information and radiology reports.

FDA: Food and Drug Administration.

Health Information Exchange (HIE): A multi-stakeholder entity that enables the movement of health-related data within state, regional, or non-jurisdictional participant groups.

Health Researchers: Organizations or individuals who use health information to conduct research.

Healthcare Entities: Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health, school health, dental clinics, psychology clinics, care delivery organizations, and other healthcare facilities.

Healthcare Payors: Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.

HITSP: Healthcare Information Technology Standards Panel.

Medical Device Manufacturers/Suppliers: Organizations that design, build, sell, or support the use of medical devices by consumers to support their health needs with coordinated assistance from clinical and other health support personnel.

ONC: Office of the National Coordinator for Health Information Technology.

Patients: Members of the public who receive healthcare services.

Personal Health Record (PHR): A health record that can be created, reviewed, annotated, and maintained by the patient or the caregiver for a patient. The personal health record may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history, or communications with healthcare providers.